

JAN 20 2012

Section 5: 510(k) Summary

Assigned 510(k) number: K112936

Company: Rexam Healthcare
800 Corporate Grove Drive
Buffalo Grove, IL 60089
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Contact: Sandra Anderson, M.J., RAC

Date Prepared: December 21, 2011

Proprietary Names: Safe'n'Sound® Luer Lock Passive Delivery System

Classification Name: Piston syringe accessory

Classification: 21 CFR 880.5860, Class II, Product Code MEG

Predicate Devices: K060743 UltraSafe® Passive Delivery System by Safety Syringes, Inc.; K101233 Safe'n'Sound® Passive Delivery System by Rexam Pharma

Device Description: The Safe'n'Sound® Luer Lock Passive Delivery System is an anti-needlestick accessory for use with BD Hypak SCF glass Prefilled Syringes. It fits with needles 1" long maximum, and consists of a body assembly and a loose plunger rod.

Intended Use: Single use devices that are indicated for use as an accessory with BD Hypak Sterile Clean Fill (SCF) glass Prefilled Syringes 1 mL long to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications, and individuals that assist self-injecting patients, from accidental needlesticks. The devices can be used on a wide range of patients including children and adults.

Technological
Characteristic Comparison
Summary to Predicate
Device: The Safe'n'Sound® Luer Lock Passive Delivery System is similar to predicate devices in general technological features and principle of operation. All are molded plastic

assemblies consisting of a body, sleeve, plunger rod, and spring that activates upon injection completion to fully contain the needle. Minor differences with the predicates in technological features and performance have been demonstrated to be insignificant based upon bench testing and simulated clinical use studies performed.

Performance Testing: Bench testing has been performed on the Safe'n'Sound® Luer Lock Passive Delivery System. It confirmed the product functions as intended and is substantially equivalent to the predicate device. Biocompatibility testing performed demonstrates that the product meets ISO 10993-5 and ISO 10993-10 requirements.

Clinical Testing: Simulated clinical use testing has been performed. It confirmed that the Safe'n'Sound® Luer Lock Passive Delivery System could be used safely and effectively to shield needles inside the protection device after use.

Conclusion: Based upon the design, technology, performance, functional testing, and intended use, the Safe'n'Sound® Luer Lock Passive Delivery System is substantially equivalent to predicate devices currently marketed under the Food, Drug and Cosmetic Act. The Safe'n'Sound® Luer Lock Passive Delivery System raises no new issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

JAN 20 2012

Ms. Sandra Anderson
Regulatory Compliance Manager
Rexam Consumer Plastics Incorporated d/b/a Rexam Pharma
800 Corporate Grove Drive
Buffalo Grove, Illinois 60089

Re: K112936
Trade/Device Name: Safe'n'Sound® Luer Lock Passive Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: December 21, 2011
Received: December 22, 2011

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112936

Device Name: Safe'n'Sound® Luer Lock Passive Delivery System

Indications for Use:

Single use devices that are indicated for use as an accessory with BD Hypak Sterile Clean Fill (SCF) glass Prefilled Syringes 1 mL long to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications, and individuals that assist self-injecting patients, from accidental needlesticks. The devices can be used on a wide range of patients including children and adults.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

 K. C. Chappin 1/12/12
(Division Sign-Off) Concurrency of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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